

# APPENDIX 3

## Responsibilities of Custodians and *Health Information Act* Administration Checklist

## APPENDIX 3

### Responsibilities of Custodians in Administering the *Health Information Act*

Each custodian under the *Act* must establish internal processes and procedures suited to the organization's size, structure, specific circumstances and anticipated workload. A custodian's responsibilities under the *Act* include:

- receiving and responding to requests for health information, meeting the duty to assist applicants and collecting any fees as set out in the *Act* (sections 7-10, 12, 15, 17 and 67);
- deciding what information will be released and what information will be excepted from disclosure under the legislation (section 11);
- receiving and responding to requests for correction or amendment (sections 13-15);
- fulfilling the various duties of the custodian relating to the collection, use, disclosure and protection of health information, including the rules regarding the least amount of information and the highest degree of anonymity (sections 18-22);
- responding to the Information and Privacy Commissioner to resolve reviews and complaints under the *Act* (sections 73-82, 84, 85); and
- assisting the public by designating one or more individuals to be responsible for the implementation and administration of the *Act* and making available any policies or procedures regarding compliance with the *Act* (sections 62 and 63).

#### ***Health Information Act* Administration Checklist For Custodians**

The following issues and tasks should be addressed by custodians when complying with the *Act*. Although they are arranged for the most part in relative priority, many of these tasks can be completed simultaneously.

##### **1. Establish the structure necessary to administer the *Health Information Act***

Designate a responsible person(s)

Custodians have a number of responsibilities and requirements related to the administration of the *Health Information Act*. Regardless of the size and structure of the custodian, fulfilling these responsibilities will require clear lines of responsibility and coordination within each organization.

Section 62 of the *Act* requires each custodian to identify an individual who will be responsible for implementing the *Act* and the regulations made under it. This individual is also responsible for ensuring that the necessary *Health Information Act* related policies and procedures are established and followed.

The *Act* provides flexibility for custodians. If the custodian organization is large or decentralized, it may choose to identify individuals responsible for the *Act* on a site by site or geographic basis, rather than having one person responsible for administration. Designated individuals may be employees or agents of the custodian. "Best

practices” point to the importance of having only one individual designated, if possible, with support from site or area/program contacts as necessary. The designated individual should have access to senior staff and decision makers and the necessary resources and support to administer the *Act* within the organization.

A single individual or agent may represent several custodians in a clinic or facility setting or in instances where custodians do not have the capacity to administer the *Act*. These arrangements should be formalized to ensure that the scope of responsibility is clear. As in other areas of the *Act*, the custodian remains ultimately responsible for the actions of their agents.

Establish an appropriate administration support team

Depending on the projected volume of requests, the amount and type of health information collected, used or disclosed, and the size and complexity of the organization, a custodian may wish to establish a team to support the person responsible for administering the *Act*. For example, in a large organization such as a health authority, the team should likely include senior representatives from the various parts of the organization affected by the *Act* (i.e. those areas that collect, use, disclose or protect health information). It may also include a representative from information technology and systems, information or records management and the legal department.

Custodians that provide a single health service or work in a clinic will have very different support needs. In these cases, support administering the *Act* is provided by professional/regulatory bodies, the Department and other support organizations.

Identify and communicate with other “affiliated” custodians

Under the *Act*, some custodians have responsibility for other custodians. For example, a regional health

authority has some level of responsibility for subsidiary health corporations, community health councils, other boards, councils, committees or agencies that they create and hospitals and nursing homes they fund to perform services in the region. In these cases, the custodian should identify all the various other custodians they are responsible for as early as possible and take steps to determine how to administer the *Act* for, or with, them.

## **2. Establish a communications plan**

The Department is responsible for overall leadership and direction in communicating with the various custodians about the *Act* and ensures that appropriate information and materials are available.

In addition, each custodian should have an internal and external communication plan in place.

The plan should include:

- key messages the custodian wishes to communicate about its responsibilities and activities in administering the *Act*; and
- activities designed to make all the patients, clients, residents, agents, and employees aware that the *Act* applies to the custodian.

## **3. Establish a training plan and conduct awareness training**

Training and awareness sessions are very important and are a requirement under the *Act*.

In medium to large organizations, the training plan should accommodate a variety of audiences and their requirements including the following:

- site or facility contacts, program contacts and back-up contacts (if required) require an in-depth knowledge of the procedural and interpretative aspects of the *Act*;
- senior staff require a general knowledge of the procedural and interpretative aspects of the *Act*, including its impact on the operations of the organization;

- members of the governing authority (e.g. boards) should understand the principles and overall approach of the Act, its general requirements and impact on the organization;
- staff who have daily contact with the public must be able to recognize and channel both health information requests and freedom of information (FOIP) requests, if applicable, to the appropriate contact points for response;
- all staff and agents of the custodian should be aware of the existence and basic requirements of the Act, their obligations under the Act, the name of the person or area(s) responsible for its administration in the organization; and
- specific staff groups, such as human resources staff, those responsible for collecting health information in admitting offices or functions, managers responsible for internal operations and support functions, information systems and information management specialists, legal advisors and others will need a detailed understanding of the Act as it relates to their specific area of expertise.

Training and awareness in small offices or organizations pose different challenges. While the person responsible for the administration of the *Act* can likely be the centre of knowledge about the *Act* in the short term, others in positions of responsibility and those who interact directly with individual patients clearly need to understand the rules in the *Act*, their obligations under the *Act*, their implications and the administrative requirements.

Training materials have been produced by the Department and are available for custodians to use in their own training programs.

#### 4. Assess the status quo

Custodians should periodically review their processes for collection, use, disclosure and protection of health information with the general requirements of the *Act* in mind. The following is a list of areas where operations may be affected as well as key questions to ask. Once again, the size and complexity of the organization will directly impact the amount of effort required to consider these areas.

Who are the affiliates of the organization?

The definition of affiliates in the *Act* includes a custodian's employees and those in a contractual or agency relationship. A list of who falls into this definition may change over time. Ensure that contracts specify whether the party is an affiliate or not based on their need to access health information. Assess which employees or agents have a role, or set of duties, in the office or organization that requires them to access identifying health information, and whether that access needs to be blanket access, or access only to some information in some circumstances. Remember to provide HIA training or awareness as required.

What are current practices?

Current practices should be periodically checked against organizational policies to ensure they reflect the requirements of the *Act*.

Consider these questions:

- Collection – What is the current authority for collection of information? Is information collected directly from the individual or from other sources (If another source, why? Under what conditions?) Is information about the collection provided to individuals at the time of collection (notification)? Are hidden cameras or other recording devices used to collect health information?

- Access – Is individual access to health information possible currently? Under what authority? At what cost? How quickly does the individual obtain access?
- Use – What is the role and mandate of the organization in relation to those purposes listed in Section 27 of the Act? Are some of the purposes listed more relevant than others? What amount and type of information is necessary to fulfill those purposes? Is more information collected or used currently than may be necessary?
- Disclosure – Where is health information disclosed? What amount and type? Under what authority? Do the disclosure sections of the Act (sections 35-37) appear to allow this type of disclosure to continue? Where required, has the individual been informed in writing of the purpose of the disclosure and the authority under which the disclosure is made?
- Disposition – How and when does health information currently get disposed of in both hard copy and electronic form?
- Data matching – Does any data matching or data linking activity currently take place? If so, with whom? Does it occur on an occasional (i.e. batch) basis or does it occur as part of a regular process? Are PIAs conducted where necessary?
- Security – How is health information currently secured in both hard copy and electronic systems? To what extent is access controlled? Is it on a “need to know” basis? How is information that is transmitted or transferred secured? Are these systems audited on a regular basis?
- Do the current records and information management systems enable the appropriate staff to locate and retrieve records containing health information about an individual in a complete, accurate and timely manner? This includes records in all formats including paper-based files, electronic patient files, electronic databases and other media. It also includes all types of files that may contain health information about an individual including the patient medical record, material waiting to be transcribed or entered into the patient record, information about the patient that may exist in other places (e.g. subject-based files on specific diseases or procedures, etc.).
- What amount and type (i.e. diagnostic treatment and care, registration and health service provider) of health information exists in the organization, in what format and where? It may also be helpful to know whether the three types of information always exist together or whether there are instances where one or more types exist apart from the others. This distinction makes it easier to determine which rules apply to which information.
- Which records in the custody or control of the organization are exempt from the Health Information Act, or otherwise covered by another Act, such as the FOIP Act?
- What are the current records retention and disposition practices (i.e. how long are the various types of health information records kept for) of the organization and what is the basis for current practice?
- What health information has been, or will be, provided for archival storage? If any information is stored in archives, it is important to be clear on who manages

What are the current practices for records management and archives?

Consider these questions:

How are Personal Health Numbers collected and used?

The *Health Information Act* intentionally limits the collection of Personal Health Numbers (PHNs). Periodically assess if PHNs are used only for the purposes for which they were collected. Is the organization advising individuals of their authority to collect PHNs before they request a PHN from an individual?

Are there other legal authorities that apply?

Any one of a number of existing statutes and/or regulations could be relevant to a custodian's operations. The *Health Information Act* allows many existing practices to continue if they are fully authorized by an existing statute or regulation.

What are the organization's policies for consent?

The *Health Information Act* is primarily consent based. Do staff know when consent for disclosure is and is not required? Does the organization use a standard consent form that includes the consent requirements as stated in the *Act*?

When are privacy impact assessments required?

Is the organization planning any new information systems, administrative practices or data matching projects? Do the initiatives relate to the collection, use, disclosure or storage of identifiable or non-identifiable health information? Do those involved in these initiatives understand the requirements of the *Act* and the impact those requirements may have on their projects?

How are the various levels of anonymity determined and achieved?

As the *Act* requires custodians to collect, use or disclose health information at the highest level of anonymity possible to achieve the intended authorized purpose, an organization must have

some ability to create or view information at various levels of anonymity. What is the current level of knowledge and ability within the organization to transform information so it can be provided at different levels of anonymity? Is the organization able to acquire those services from another source?

How are contracts developed and managed?

Contractors providing services, including information services, to the custodian are constrained in many areas under the *Act*. The terms of the contract or agreement between the parties are important to establish roles and responsibilities relative to the various dimensions addressed in the *Act*.

##### **5. Develop/maintain procedures for tracking and responding to health information requests**

The *Health Information Act* sets out time limits for processing and responding to requests for health information and corrections, calculating fees and defending decisions and actions if there is an appeal to the Information and Privacy Commissioner. The person responsible for administering the *Act* needs to ensure that the organization's policies and procedures can meet the prescribed time limits.

Periodically assess if the organization's procedures and assigned responsibilities generally address:

- receiving requests for health information and corrections;
- creating a request file;
- accepting verbal and written requests;
- locating and retrieving health information records;
- administering fees;
- applying exceptions to the right of access;
- severing records;
- responding to applicants;

- explaining terms, codes and abbreviations used in the records;
- closing the request file;
- preparing for a review by the Office of the Information and Privacy Commissioner; and
- determining what information will be available without a request under the Health Information Act.

**6. What is the organization’s plan for ensuring compliance with the privacy provisions of the Act?**

The person responsible for administering the *Act* must ensure that the business practices of the organization are periodically reviewed in order to meet the requirements of the *Act*. Any new practices should be based on the provisions in the *Act* and on regulations under the *Act*.

Business practices involving the collection, use, disclosure, disposition and security of health information will vary among custodians depending on the size, complexity and administrative structure of the organization. Do the policies, practices and assigned responsibilities generally address:

- assessing the least amount of information required;
- assessing the highest degree of anonymity of information required and how information can be transformed;

- ensuring that the expressed wishes of individuals are considered;
- ensuring adequate safeguards;
- ensuring accuracy of information;
- providing notification at disclosure of data matching and authority/purpose statements;
- providing notations of disclosure of records of individually identifying diagnostic, treatment and care information;
- establishing procedures for authenticating the identity of individuals and recipients;
- providing for compulsory disclosure and appeals;
- establishing research review processes and agreements;
- establishing policies for collection and use of Personal Health Numbers;
- defining employee and agent authority regarding identifying health information;
- establishing the obligations for protecting health information under its custody and control; and
- assessing privacy impact of new systems, practices and data matching proposals.

# APPENDIX 3

## Health Information Act Administration Checklist

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### 1. Establish the structure necessary to administer the *Health Information Act*

- Designate a responsible person(s)
- Establish an appropriate implementation support team
- Identify and communicate with other “affiliated” custodians (e.g. subsidiary health corporations, community health councils, etc. for which a regional health authority has responsibility)

### 2. Establish a communications plan

### 3. Establish a training plan and conduct awareness training

- Medium to large organizations
- Small offices and organizations

### 4. Assess the status quo

- Who are affiliates (employees/agents) and what are their duties?
- What are current collection, access, use, disclosure, disposition, data matching and security policies and practices?
- What are the records management and archives practices
- What amount and type of health information exists?
- Will some records be exempt from the Health Information Act or subject to other Acts?
- Current records retention/disposition practices and basis?

- Any information provided for archival storage – how is it managed?
- If the Personal Health Number is collected, how is it used?
- Are there other legal authorities that apply?
- What are the organization’s policies on consent?
- When are PIAs required?
- Anonymity transformation knowledge and ability?
- Contracting practices/contractor obligations?

### 5. Develop/maintain procedures for tracking and responding to access requests

- Receipt of health information and correction requests
- Creation of a request file
- Acceptance of verbal and written requests
- Locating and retrieving health information records
- Fee administration
- Application of exceptions to the right of access
- Severing records
- Responding to applicants
- Explanation of terms, codes and abbreviations used in the records
- Closure of a request file
- Preparation for review by the Information and Privacy Commissioner

- Determine what information will be available without a request under the Health Information Act

**6. Develop/maintain a plan to ensure compliance with the privacy provisions of the Act**

- Least amount of information assessment
- Highest degree of anonymity assessment and transformation
- Express wishes administration
- Adequate safeguards
- Ensuring accuracy
- Notification at disclosure
- Notation of disclosure

- Recipient authentication practices and policies
- Compulsory disclosure and appeals
- Research review processes and agreements
- Personal Health Number use administration
- Defining employee and agent authority re: identifying health information
- Duty to protect obligations for health information under its custody and control
- Assessing privacy re: new systems, practices and data matching proposals

# APPENDIX 4

## Components for Agreements Under the *Health Information Act*

# APPENDIX 4

## Components for Agreement with Information Manager

### (Section 66 of the *Health Information Act*)

Note that this document is intended to be used only as a checklist of components for an Agreement with an Information Manager under section 66. It does not constitute a precedent or legal advice. Parties to the Agreement need to determine what provisions should be in the Agreement, giving consideration to their relationship and the tasks that the Information Manager will perform.

### INTRODUCTORY MATTERS

1. Correct legal names of parties, verified by Corporate Registry Search, if necessary.
2. Authority to enter Agreement – section 66 of the *Health Information Act*.
3. Duration or Term of Agreement (see clause 20).

### SERVICES TO BE PROVIDED

4. Description of services to be provided by Information Manager including any transformation of information services.
5. Description of health information that is the subject of the Agreement.
6. Financial arrangements – could be attached as a schedule.

### RESPONSIBILITIES OF INFORMATION MANAGER

7. The Information Manager must comply with the *Health Information Act*, the regulations under the *Act* and the terms and conditions of the Agreement with respect to the information disclosed to it by the custodian.

8. The Information Manager may use health information only for the purposes specified in the Agreement, unless the custodian has given prior written authorization for additional uses.
9. The Information Manager may disclose health information only in accordance with the Agreement and only according to the disclosure rules and processes for custodians outlined in the *Act*.
10. The Information Manager must comply with the terms and conditions relating to the type of records storage media, the length of time the information is to be retained and the method of disposition to be used in destroying or archiving the information.
11. The Information Manager and its employees, agents and contractors must only modify the information in accordance with the terms of the Agreement.
12. The Information Manager must protect the information against such risks as unauthorized access, use, disclosure, loss, destruction, or alteration and limit “access” to the information only to those employees, agents or contractors who have a need to know. The Information Manager must comply with the requirements of section 60 of the *Health Information Act* and section 8 of the Health Information Regulation relating to the security of health information (could attach a copy of the Regulation as a schedule to the Agreement). Pursuant to section 8(4) of the Health Information Regulation, the Information Manager may have

to enter into an additional agreement if information is being stored used or disclosed outside of Alberta. Additional concerns regarding the application of the *U.S.A. PATRIOT Act* are raised if information is being stored used or disclosed in the United States or if the Information Manger is a U.S.A. company. As well, the *PATRIOT Act* may apply if the Information Manger's parent company or affiliated companies are based in the United States.

13. The Information Manager must notify the custodian in writing immediately if the Information Manager or its employees, agents or contractors become aware that any of the conditions set out in the Agreement have been breached.
14. The recorded information held by the Information Manager is under the custody or control of the custodian for the purposes of the *Health Information Act*.
15. The Information Manager Agreement should specify:
  - whether or not the information manager is permitted to collect health information from any other custodian or from a person and, if so, describe that health information and the purpose for which it may be collected,
  - the process for the information manager to respond to requests to amend or correct health information under Part 2 of the Act or, if the information manager is not to respond to requests to amend or correct health information, describe the process for referring access requests to amend or correct health information to the custodian itself,
  - describe how the information manager is to address an expressed wish of an individual relating to the disclosure of that individual's health information or, if the information

manager is not to address an expressed wish of an individual relating to the disclosure of that individual's health information, describe the process for referring these requests to the custodian itself.

16. Requests by individuals, or their authorized representatives, to access information held by the Information Manager will be directed to and handled by the custodian, but the Information Manager will have a specified role in the retrieval of the requested information for the custodian. (Timelines and costs for retrieval should be indicated and in keeping with the provisions of the Act and Regulations. The timeline for retrieving the requested information and providing it to the custodian should be relatively short i.e. 4-5 days to fit within the 30 day timeline in the Act.)

## **INDEMNITY AND HOLD HARMLESS**

17. The Information Manager must agree to be fully and solely responsible for the actions of its employees, agents, contractors, consultants and other persons respecting the use or disclosure of the information and for any unauthorized disclosure or use of the information as a result of carrying out the Agreement, regardless of the cause (including, but not limited to, negligence, misfeasance, malfeasance, accident or neglect) during the term of the Agreement or after the expiration or earlier termination of the Agreement.
18. The Information Manager must agree to hold the custodian harmless from any third party claims, demands or actions for which the Information Manager is legally responsible, including those arising out of negligence, willful harm or crimes by the Information Manager or its employees, agents or contractors.
19. The Information Manager must agree to indemnify the custodian for any and all costs or

expenses paid or incurred by the custodian as a result of any breach of any term or condition of this Agreement or contravention of the *Act* or regulations or arising out of any disclosure by the Information Manager, its employees, agents or contractors of the health information that is subject to this Agreement in any manner contrary to the Agreement. Such indemnification will survive the termination of the Agreement.

20. The custodian is not responsible for any bodily or personal injury or property damage or business losses that may be suffered or sustained by the Information Manager, its employees, agents or contractors in the performance of the Agreement.

#### **TERM AND TERMINATION**

21. The Agreement should specify a Term including a date on which the Agreement commences and the Agreement's duration or specified end date. The Agreement may also contain provisions concerning possible Term renewals.
22. The Agreement may be terminated by either party under certain conditions prior to completion of the Term.

23. In the event the Agreement is breached and/or health information is disclosed or used in contravention of the terms and conditions of the Agreement or the *Act* or regulations, the Agreement may be immediately terminated by the custodian and the Information Manager may be found guilty of an offence under section 107 of the *Act*.

#### **GENERAL PROVISIONS**

24. The Agreement may only be amended or varied in writing with the mutual agreement of the parties.
25. The parties must each designate an individual for responsibility for the Agreement, notices and communications (include the contact information for the designated individuals).

#### **EXECUTION**

- The Agreement must be signed by officers or other officials of the parties who have authority from the parties to sign such an agreement.

# APPENDIX 4

## Components for a Research Agreement

(Section 54 of the *Health Information Act*)

Note that this document is intended for use only as a checklist of components for a Research Agreement under Section 54. It does not constitute a precedent or legal advice. Parties to the agreement need to determine what provisions should be in such an agreement, giving consideration to their relationship and the tasks that the researcher will perform.

Where the researcher is an affiliate of the custodian (employee or physician with privileges), the agreement may need to be modified depending upon the nature of the relationship between the custodian and the affiliate.

### INTRODUCTORY MATTERS

1. Names of parties to the agreement.
2. Identification of lead researcher who is bound by this agreement.
3. Statement that the researcher has applied to the custodian for disclosure of health information for the research purposes (as listed in Schedule A – application for disclosure of health information to be used in research including the research purpose(s)) (section 52).
4. Description of Research Project (reference to Schedule B - full research proposal or summary of the research proposal).
5. Statement that the Research Ethics Board is satisfied that the researcher has met the requirements of section 50 (the Research Ethics Board must be designated by the Minister in the Health Information Act Designation Regulation). Include the name of the designated ethics committee that reviewed the proposed research project and when approval was granted.
6. Statement that the custodian has decided to disclose the health information applied for to the researcher (section 53).
7. Statement that the researcher will or has obtain(ed) the consents of the individual subjects prior to disclosure of their health information, if obtaining consents was recommended by the ethics committee (section 50(1)(a)).
8. Duration of Research Project and duration of the Research Agreement. (Could add an ability to extend the time limits with consent of the custodian).

### RESPONSIBILITIES OF RESEARCHER

9. The researcher agrees to comply with:
  - the *Health Information Act* and all regulations under that *Act* (section 54(1)(a)(i));
  - any conditions imposed by the custodian relating to the use, protection, disclosure, return or disposal of the health information (section 54(1)(a)(ii)); and
  - any requirements of custodian to provide safeguards against the identification, direct or indirect, of an individual who is the subject of the health information (section 54(1)(a)(iii)).
10. The researcher understands that if he/she knowingly breaches the terms and conditions of the research agreement, he/she is guilty of an offence and liable to a fine of up to \$50,000 (section 107(3) and (6)).

## **RESPONSIBILITIES OF CUSTODIAN**

11. The custodian agrees to disclose the research information or data in a specific format at specific time(s) (reference to Schedule C – specifics of the research information (data sources/elements) and any other information to be disclosed).
12. The custodian agrees to obtain consents to contact the individuals who are the subject of the information to obtain additional data. (Alternatively, this clause could bar the researcher from any further contact, depending on the nature of the research) (section 55 or section 54(1)(d)).

## **RESTRICTIONS ON USE AND DISCLOSURE OF HEALTH INFORMATION**

13. The researcher agrees to only use the research information (data sources/elements) and any other information disclosed by the custodian (reference Schedule C) for the purposes as identified in Schedule A (section 54(1)(b)).
14. The researcher agrees not to use or disclose the information for any subsequent or other purposes not identified in Schedule A without the prior written approval of the custodian (and/or the consent of the individual who is the subject of the information, if required by the custodian). The custodian may arbitrarily withhold consent for subsequent uses (section 54(1)(b)).
15. The researcher agrees to disclose information only to individuals working with the researcher on the research project (include names or positions of individuals working with researchers).
16. The researcher agrees to ensure that all individuals on the research team that have access to the information are complying with

the *Health Information Act* and regulations and with any conditions and/or requirements imposed on the researcher by the custodian (section 54(1)(a)).

## **PUBLICATION OF RESULTS**

17. The researcher agrees that no identifying information or information that could be manipulated to identify any individual will be published (section 54(1)(c)).
18. The researcher agrees to provide the custodian with the proposed report (or publication) of the results of the research for the custodian's review and the custodian agrees to acknowledge its receipt. The report (or publication of results) must include a statement that some of the information used in this study was provided by the custodian and the custodian expresses no opinion on the interpretations and conclusions in this publication.

## **REQUIREMENTS TO SAFEGUARD DATA**

19. The researcher agrees to adequately safeguard the confidentiality and security of the information obtained from the custodian (Depending on the nature of the research and the data management/manipulation that the researcher will be undertaking, specific requirements for safeguards could be added or referenced in a separate Schedule, including physical, technical, administrative and other security safeguards). The researcher also agrees to safeguard the privacy of the individuals who are the subjects of the information by ensuring that the individuals who are the subjects of the information cannot be identified, directly or indirectly (section 54(1)(a)(ii) and (iii)).
20. The researcher agrees to report to the custodian any breaches of confidentiality and/or security respecting the information; and to take

steps to both remedy the breach and prevent a similar occurrence in the future (section 54(1)(a)(ii) and (iii)).

21. The researcher agrees to allow the custodian to access or inspect the researcher's premises to confirm that the researcher is complying with the *Act* and regulations, any imposed conditions on use, protection, disclosure, return or disposal of the information and any requirements related to the provision of security safeguards (section 54(1)(e)).
22. The researcher agrees to dispose of the information after the research has been completed (set out time period for disposal) by destroying it (indicate method(s) of destruction for both paper and electronic information and electronic storage devices) or by returning it to custodian (set out time period for return).

## **FINANCIAL ARRANGEMENTS**

23. The researcher agrees to pay the custodian the amount of x\$, as detailed in Schedule C (which gives details the costs of the researcher (could include cost of information preparation, transmission, copying, and/or obtaining consents) (section 54(3)). Note that these provisions may not apply to sponsored research – a separate agreement with the sponsor will cover the financial arrangements.

## **TERMINATION**

24. In the event the agreement is breached and/or health information is disclosed or used in contravention of the terms and conditions of the agreement or the *Act* or the regulations, the agreement may be immediately cancelled by the custodian, the research privileges of the researcher may be withdrawn, all research information will need to be returned to the custodian and the researcher may be found guilty of an offence under section 107 of the *Act*.

25. The agreement may be terminated by either party under certain conditions prior to its completion.

## **INDEMNITY**

26. The researcher agrees to hold the custodian harmless from any third party claims, demands or actions for which the researcher is legally responsible, including those arising out of negligence, willful harm or crimes by the researcher (or its employees or agents, if any).
27. The researcher agrees to indemnify the custodian for any and all costs or expenses paid or incurred by the custodian as a result of any breach of any term or condition of this Agreement or contravention of the *Act* or a regulation under the *Act* or arising out of any unauthorized disclosure by the researcher of the health information that is subject to this Agreement in any manner contrary to the Agreement. Such indemnification will survive the termination of the Agreement.
28. The custodian is not responsible for any bodily or personal injury or property damage or business losses that may be suffered or sustained by the researcher (or its employees or agents, if any) in the performance of the Agreement.
29. The researcher has no recourse against the custodian for any loss or damage arising from the researcher's interpretation or analysis of the information received from the custodian or from the conclusions reached by the researcher. The researcher has no recourse against the custodian for any loss or damage arising from any advice provided by the custodian about the research information.

Where the researcher is an affiliate of the custodian (employee or physician with privileges), the indemnity provisions may need to be modified or deleted depending upon the nature of the affiliate's relationship to the custodian.

## **TERMINATION OF AGREEMENT**

30. Statement of the conditions under which the custodian can terminate the agreement, including retention, disposition or return of the information if the agreement is terminated prior to the completion of the research. In some cases, data must be retained for a fixed period (e.g. 7 to 15 years).
31. Statement of the conditions under which the researcher can terminate the agreement prior to the completion of the research, including the responsibility to inform the custodian to cease information disclosure (method of notifying custodian, time periods, etc.).

## **OTHER GENERAL PROVISIONS**

32. The researcher agrees that the consent of the custodian has been obtained prior to the transfer of the agreement to another person. Consent may be arbitrarily withheld in the discretion of the custodian. Successors must be bound by the terms and conditions of the agreement.

Note that if the research agreement is with an individual researcher rather than a corporate entity, the agreement should not be transferable.

33. For any required notices (regarding publication, termination, etc.) under the agreement, the contact information of designated officials of the parties should be listed
34. Provide for the signatures of officials who are authorized by the parties to sign the agreement.
35. Include any other legally required provisions.